KURZPROTOKOLL
SGNTUC-016

Öffentlicher Titel	Phase III Studie zu Tucatinib und Ado-Trastuzumab Emtansin als Zweitlinientherapie bei metastisierendem oder nicht-resezierbarem Brustkrebs
Wissenschaftl. Titel	Randomized, double-blind, phase 3 study of tucatinib or placebo in combination with ado -trastuzumab emtansine (T-DM1) for subjects with unresectable locally-advanced or metastatic HER2+ breast cancer
Kurztitel	SGNTUC-016
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, zweiarmig, einfach verblindet
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	- Histologically confirmed HER2+ breast carcinoma as determined by a sponsor-designated central laboratory - History of prior treatment with a taxane and trastuzumab in any setting, separately or in combination - Have progression of unresectable locally advanced/metastatic breast cancer after last systemic therapy, or be intolerant of last systemic therapy - Measurable or non-measurable disease assessable by RECIST v1.1 - ECOG performance status score of 0 or 1 - CNS Inclusion - Based on screening contrast brain magnetic resonance imaging (MRI), subjects must have at least one of the following: (a) No evidence of brain metastases (b) Untreated brain metastases not needing immediate local therapy (c) Previously treated brain metastases Brain metastases previously treated with local therapy may either be stable since treatment or may have progressed since prior local CNS therapy, provided that there is no clinical indication for immediate re-treatment with local therapy Subjects treated with CNS local therapy for newly identified lesions or previously treated and progressing lesions may be eligible to enroll if all of the following criteria are met: (i) Time since SRS is at least 7 days prior to first dose of study treatment, time since WBRT is at least 21 days prior to first dose, or time since surgical resection is at least 28 days. (ii) Other sites of evaluable disease are present Relevant records of any CNS treatment must be available to allow for classification of target and non-target lesions
Ausschlusskriterien	- Prior treatment with tucatinib, afatinib, trastuzumab deruxtecan (DS-8201a), or any other investigational anti-HER2, anti-EGFR, or HER2 TKI agent. Prior treatment with lapatinib or neratinib within 12 months of starting study treatment (except in cases where they were given for <=21 days and was discontinued for reasons other than disease progression or severe toxicity). Prior treatment with pyrotinib for recurrent of mBC (except in cases where pyrotinib was given for <=21 days and was discontinued for reasons other than disease progression or severe toxicity) - CNS Exclusion - Based on screening contrast brain magnetic resonance imaging (MRI), subjects must not have any of the following: Any untreated brain lesions >2 cm in size Ongoing use of corticosteroids for control of symptoms of brain metastases at a total daily dose of >2 mg of dexamethasone (or equivalent). Any brain lesion thought to require immediate local therapy Known or concurrent leptomeningeal disease as documented by the investigator Poorly controlled generalized or complex partial seizures
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Sponsor	Seagen
Registrierung in anderen Studienregistern	EudraCT 2019-005017-39 ClinicalTrials.gov NCT03975647 (primäres Register)